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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,254	08/01/2006	Leon Rudakov	077567-0035	1195

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EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	
MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,254	RUDAKOV ET AL.	
	Examiner	Art Unit	
	Megan Wolf	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/29/05* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *042307,082808,101008,122408,083109*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the features of the delivery catheter claimed in claims 14 and 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is directed to a device but line 4 of the claim positively recites a step of expanding the stent ("is expanded"). This limitation was interpreted by the examiner to mean that the device is capable of being expanded.

Similarly, claims 12-15 positively claim steps of implanting the polymer and chemical compound which is unclear in an apparatus claim. Claim 12 says that the compound and polymer "are released". Correction is required.

Claims 10 and 12-15 are also unclear because they are directed to an embodiment wherein the chemical compound and polymer are separate from the stent. Yet, claim 1 is directed to "a medical device for insertion into a bodily vessel", which the examiner believes implies that the device is a stent comprising the features claimed. Please clarify.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6-9, 21, 22, and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Greene et al. 2002/0120276.

Re claim 1, Greene discloses a medical device for insertion into a bodily vessel to treat an aneurysm having an aneurysm neck, the device comprising a mechanically expandable device 60 expandable from a first position to a second position, said mechanically expandable device is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel (par.88; fig.13) a therapeutically effective amount of a chemical compound comprising a biosynthesis accelerator to stimulate cell growth (par.54) and a polymer mixed with the chemical compound to manage the release rate of the chemical compound (pars.50-51) wherein the mechanically expandable device provides a support for the release of the chemical compound within the aneurysm to stimulate cell growth within the aneurysm and close the aneurysm neck.

Re claims 6-9, the polymer pellets are PVA hydrophilic hydrogels (pars.50-51).

Re claims 21 and 22, see par.53.

Re claims 25-28, see fig.13 and par.88.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-5, 8, 9, and 16-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chatterjee 6,511,979.

Re claim 1, Chatterjee discloses a medical device comprising a therapeutically effective amount of a chemical compound comprising a biosynthesis accelerator to stimulate cell growth (col.7, ll.25-29) and a polymer mixed with the chemical compound to manage the release rate of the chemical compound (col.9, ll.31-35). Chatterjee further discloses that the chemical compound and polymer may be delivered by a stent but does not specifically state that the stent is a mechanically expandable device expandable from a first position to a second position, the mechanically expandable device expandable radially outwardly to the second position such that the exterior surface of the mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through the vessel. However, this is the general description of well known vascular stents. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to construct the stent as an expandable device in order to deliver and deploy the device in the vessel. The stent comprising the chemical compound and coating of Chatterjee are capable of providing a support for the release of the chemical compound within the aneurysm to stimulate cell growth within the aneurysm and close the aneurysm neck.

Re claims 2-5, the chemical compound of Chatterjee may be L-PDMP (col.7, ll.25-29; clm.3) and functions as claimed (col.2, ll.60-65).

Re claims 8 and 9, see col.9, ll.31-35.

Re claims 16-19, Chatterjee discloses that the chemical compound and biodegradable polymer may be delivered by a stent (col.9, ll.47-50). Note that the polymer must either be porous or solid.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee as applied to claim 16 above, and further in view of Hossainy et al. 2004/0220665. Chatterjee discloses the invention substantially as claimed and as discussed above but does not specifically disclose that the drug delivering polymer is amorphous or semi-crystalline.

Hossainy teaches a drug delivery stent, in the same field of endeavor, wherein the polymeric membrane is semi-crystalline for the purpose of allowing for the active agent to diffuse out of the polymer (pars.44-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the polymer of Chatterjee be at least semi-crystalline in order to allow the L-PDMP to diffuse out of the polymer and into the region that requires treatment.

9. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee as applied to claim 1 above, and further in view of Hyodoh et al. 2003/0040772. Chatterjee discloses the invention substantially as claimed and as discussed above but does not disclose that the stent is biodegradable or that the stent and polymer degrade at different rates.

Hyodoh teaches a stent, in the same field of endeavor, wherein the stent is biodegradable for the purpose of preventing the formation of emboli (par.210).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Chatterjee to be biodegradable in order to allow for the stent to degrade within the bloodstream over a period of time to prevent the formation of

emboli. It would have been further obvious that the stent degrade at a slower rate than the polymer delivering L-PDMP in order to allow the necessary amount of active agent to be released prior to the degradation of the stent. Further, the different degradation rates are a matter of design choice that was not disclosed as being critical to the practice of the invention.

10. Claims 2-5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene as applied to claim 1 above, and further in view of Chatterjee 6,511,979. Greene discloses the invention substantially as claimed and as discussed above but does not disclose that the chemical compound is L-PDMP.

Chatterjee teaches a drug delivery device, in the same field of endeavor, wherein the cell growth stimulating agent is L-PDMP for the purpose of increasing proliferation of cells (col.7, ll.25-49).

Therefore, because Greene teaches a cell growth promoting agent in combination with a polymer located on platinum coils (par.15), it would have been obvious to use L-PDMP for the therapeutic agent, for the purpose of increasing proliferation of cells as taught by Chatterjee.

11. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene as applied to claim 1 above, and further in view of Escamilla 2004/0078071.

Re claim 11, Greene discloses the invention substantially as claimed but does not disclose that the stent has a plurality of interconnected struts having interstitial spaces therebetween.

Escamilla teaches a vascular prosthesis, in the same field of endeavor, wherein the stent comprises an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween for the purpose of supporting the lumen (fig.11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Greene to include interconnecting struts as taught by Escamilla as interconnected struts are very well known in the art for providing expansion and support in the vessel.

Re claims 12-15, the intended use of the device is given little patentable weight. Still, the coil containing cylinders of the polymer and chemical compound are capable of being released by a catheter having the features claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738